APR - 8 2004

K033770

510(k) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):	IsoAid, LLC 7824 Clark Moody Blvd. Port Richey, FL 34668 Phone: 727-815-3262 Fax: 727-815-1972
Contact Person:	Max Taghizadeh
Date of Summary:	October 31, 2003
Trade Name:	IsoAid Palladium Brachytherapy Seeds
Classification:	Class II, Classification number is 90 KXK
Classification Name:	Brachytherapy, Radionuclide
Predicate Device:	TheraSeed Palladium-103 Model 200 Implant
Device Description/Comparison:	The IsoAid palladium-103 seeds are spherical sealed sources of palladium-103. The outer capsule of the source is sealed titanium. The specifications for the IsoAid device are the same as for the predicate.
Intended Use:	The ISOAID Palladium Brachytherapy Seeds is intended for the treatment of selected localized tumors. The devices are implanted as a source of nuclear radiation for therapy.

K033770

Comparison Chart

	IsoAid Brachytherapy Seeds	TheraSeed Palladium-103 Model 200
510(k) Number	To Be Determined	K010283
Indications for Use	Brachytherapy for localized tumors	Same
Capsule	Titanium	Same
Capsule Sealing Method	Laser Weld	Same
Half-Life	17.0 days	Same
Length	4.5 mm	Same
Outside Diameter	0.8 mm	Same
Application Method	Through an 18 gauge needle	Same
Apparent Activity	0.10 to 5.0 mCi	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2004

Mr. Max Taghizadeh
President
IsoAid, LLC
7824 Clark Moody Boulevard
PORT RICHEY FL 34668

Re: K033770
Trade/Device Name: IsoAid Advantage Pd-103
Regulation Number: 21 CFR §892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: March 12, 2004
Received: March 15, 2004

Dear Mr. Taghizadeh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) Number (if known): K033770

Device Name:

Advantage™ Pd-103

Indications For Use:

The IsoAid Palladium Brachytherapy Seed is intended for the treatment of selected localized tumors. The devices are implanted as a source of nuclear radiation for therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR Over the Counter Use_____
(per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033770